L6: Entry 7 of 14 File: USPT Mar 2, 1999

US-PAT-NO: 5876759
DOCUMENT-IDENTIFIER: US 5876759 A

TITLE: Rapidly disintegrating pharmaceutical dosage form and process for preparation thereof

DATE-ISSUED: March 2, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Gowan, Jr.; Walter G.	Lansdale	PA		

US-CL-CURRENT: 424/494; 424/470, 424/497

CLAIMS:

What is claimed is:

1. A compressed pharmaceutical dosage form, comprising:

at least one coated particle comprising at least one pharmaceutical coated with a taste-masking coating comprising a blend of a first polymer selected from the group consisting of a cellulose acetate and cellulose acetate butyrate and a second polymer selected from the group consisting of polyvinyl pyrrolidone and hydroxypropyl cellulose, wherein the weight ratio of the first polymer to the second polymer is within the range of about 90:10 to about 50:50;

a water-disintegrateable, compressible carbohydrate selected from the group consisting of mannitol, sorbitol, dextrose, sucrose, xylitol, lactose and mixtures there of; and

a binder selected from the group consisting of cellulose, polyvinyl pyrrolidone, starch, modified starch and mixtures there of, said dosage form having a hardness of about 1.0 to 3.0 kp wherein said carbohydrate disintegrate in the oral cavity within 30 second after oral administration thereby allowing said coated particle to be swallowed.

2. The pharmaceutical dosage form of claim 1 wherein the coated particles comprises about 5 to about 60 percent by weight of the blend of first and second polymers.

3. The pharmaceutical dosage form of claim 1 wherein the pharmaceutical is selected from the group consisting of acetaminophen, ibuprofen, flurbiprofen, naproxen, aspirin, pseudoephedrine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan, diphenhydramine, famotidine, loperamide, ranitidine, cimetidine, astemizole, terfenadine, terfenadine carboxylate, cetirizine, mixtures thereof and pharmaceutically acceptable salts thereof.

4. The pharmaceutical dosage form of claim 3 wherein the pharmaceutical is selected from the group consisting of acetaminophen, ibuprofen, loperamide, famotidine and aspirin.

5. The pharmaceutical dosage form of claim 1 wherein the blend comprises cellulose acetate and polyvinyl pyrrolidone.

6. The pharmaceutical dosage form of claim 1 wherein the blend comprises cellulose acetate and hydroxy-propyl cellulose.

7. The pharmaceutical dosage form of claim 1 wherein the blend comprises cellulose acetate butyrate and hydroxypropyl cellulose.

8. The pharmaceutical dosage form of claim 1 wherein the blend comprises cellulose acetate butyrate and polyvinyl pyrrolidone.

9. The pharmaceutical dosage form of claim 1 wherein the blend of first and second polymers is sprayed onto the pharmaceutical in a fluidized bed.

10. A compressed pharmaceutical wafer, comprising:

coated particles comprising at least one pharmaceutical coated with a blend of a first polymer selected from the group consisting of a cellulose acetate and cellulose acetate butyrate and a second polymer selected from the group consisting of polyvinyl pyrrolidone and

hydroxypropyl cellulose, wherein the weight ratio of the first polymer to the second polymer is within the range of about 90:10 to about 50:50;

a water-disintegratable, compressible carbohydrate selected form the group consisting of mannitol, sorbitol, dextrose; sucrose, xylitol, lactose, and mixtures thereof; and

a binder selected form the group consisting of cellulose, polyvinyl pyrrolidone, starch, modified starch and mixtures thereof, said wafer having a hardness within the range of about 1.0 to about 3.0 kp whereby said carbohydrate disintegrates in the oral cavity within 30 seconds after oral administration allowing said coated particles to be swallowed.

11. The wafer of claim 10 having a diameter of about 7/16 to about 3/4 inch, a thickness of about 0.05 to about 0.5 inch, and a hardness of about 1.5 to about 2.5 kp.

12. The wafer of claim 11 comprising:

about 0.5 to about 600 mg of said coated particles;

about 250 to about 750 mg of said carbohydrate; and

about 20 to about 100 mg of said binder.

13. The wafer of claim 12 further comprising:

about 4 to about 60 mg of a lubricant;

about 1 to about 10 mg of a color;

about 1 to about 10 mg of a sweetener; and

about 1 to about 10 of a flavor.

14. The wafer of claim 12 wherein the coated particle comprises about 5 to about 60 percent by weight of the blend of first and second polymers.

15. The wafer of claim 14 wherein the pharmaceutical is selected from the group consisting of acetaminophen, ibuprofen, flurbiprofen, naproxen, aspirin,

pseudoephedrine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan, diphenhydramine, famotidine, loperamide, ranitidine, cimetidine, astemizole, terfenadine, terfenadine carboxylate, cetirizine, mixtures thereof and pharmaceutically acceptable salts thereof.

16. The wafer of claim 15 wherein the pharmaceutical is selected from the group consisting of acetaminophen, ibuprofen, loperamide, famotidine and aspirin.

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Gowan, Jr.; Walter G.	Lansdale	PA		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
McNeil-PPC, Inc.	Skillman	NJ			02

APPL-NO: 08/ 842597 [PALM]
DATE FILED: April 16, 1997

PARENT-CASE:
This is a continuation of application Ser. No. 08/566,649, filed Dec. 4, 1995 now abandoned, which is a continuation of application Ser. No. 08/097,806, filed Jul. 27, 1993, now abandoned.

INT-CL: [06] A61 K 9/26

US-CL-ISSUED: 424/494; 424/470, 424/497
US-CL-CURRENT: 424/494; 424/470, 424/497

FIELD-OF-SEARCH: 424/470, 424/480, 424/482, 424/494, 424/497

PRIOR-ART-DISCLOSED:

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ART-UNIT: 191

PRIMARY-EXAMINER: Venkat; Jyothsan

ABSTRACT:

The present invention relates to a compressed pharmaceutical dosage form containing pharmaceutical particles coated with a taste-masking composition, a water-disintegratable, compressible carbohydrate and a binder. These components are dry blended and compressed into a dosage form, such as a tablet, having a hardness sufficient to cause the carbohydrate to disintegrate within 30 seconds after oral administration, thereby allowing the coated particles to be swallowed.

16 Claims, 0 Drawing figures

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US-PAT-NO: 5876752
DOCUMENT-IDENTIFIER: US 5876752 A

TITLE: Use of interfacially-polymerized membranes in delivery devices

DATE-ISSUED: March 2, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Herbig; Scott Max	Bend	OR		
Korsmeyer; Richard Wilker	Old Lyme	CT		
Thombre; Avinash Govind	Gales Ferry	IN		

US-CL-CURRENT: 424/473; 424/461, 424/464, 424/465, 424/468, 424/480, 424/481, 424/489, 424/499

CLAIMS:

We claim:

1. A device for controlled release of one or more active substances into an environment of use, said device comprising a core of said active substance, with or without one or more excipients, surrounded by a porous substructure consisting of one or more cellulose derivatives, which substructure supports one or more interfacial membranes formed thereon by a condensation reaction, said porous substructure having a composition different from said interfacial membrane.

2. A device of claim 1, wherein the interfacial membrane is permeable and imperforate.

3. A device of claim 1, wherein the interfacial membrane is permeable and perforate.

4. A device of claim 2, wherein the release is substantially osmotic pumping.

5. A device of claim 2, wherein the release is substantially diffusion.

6. A device of claim 3, wherein the release is

substantially osmotic pumping.

7. A device of claim 3, wherein the release is substantially diffusion.

8. A device of claim 1, wherein the porous substructure is cellulose ester or ethyl cellulose and the interfacial membrane is a polyamide, polyurea, polyester or polyurethane.

9. A device of claim 1, which is a tablet, capsule or bead.

10. A device of claim 1, wherein the interfacial membrane is semipermeable and imperforate.

11. A device of claim 10, wherein the release is substantially by osmotic pumping.

12. A device of claim 11, which is a capsule, tablet or bead.

13. A tablet, capsule or bead for administration to an animal which releases one or more pharmaceutically active substances into said animal over an appreciable time interval which comprises a core of said pharmaceutically active substances, with or without one or more pharmaceutically acceptable excipients, said core being surrounded by a porous substructure consisting of one or more cellulose derivatives, which substructure supports one or more interfacial membranes formed thereon by a condensation reaction, said porous substructure having a composition different from said interfacial membrane.

14. A tablet, capsule or bead of claim 13, wherein the administration is oral and the release is into the fluid of the gastrointestinal tract of said animal.

15. A tablet, capsule or bead of claim 14, wherein the substance is an antihypertensive selected from the group consisting of prazosin, nifedipine, trimazosin and doxazosin.

16. A tablet, capsule or bead of claim 14, wherein said substance is an antianxiety agent selected from the group consisting of hydroxyzine and sertraline.

17. A tablet, capsule or bead of claim 14, wherein said substance is the anticlotting agent dazmegrel.

18. A tablet, capsule or bead of claim 14, wherein said substance is the hypoglycemic agent glipizide.

19. A tablet, capsule or bead of claim 14, wherein said substance is cough or cold agent selected from the group consisting of brompheniramine, dexbrompheniramine maleate, chlorpheniramine maleate, phenylephrine hydrochloride, pseudoephedrine hydrochloride or cetirizine.

20. A method for releasing one or more active substances into an environment of use which comprises placing in said environment a device containing said active substances surrounded by a porous substructure consisting of one or more cellulose derivatives, which substructure supports an interfacial membrane formed thereon by a condensation reaction, said porous substructure having a composition different from said interfacial membrane.

21. A method of claim 20, wherein the device is a tablet, capsule or bead.

22. A method of claim 20, wherein the interfacial membrane is permeable and imperforate or perforate.

23. A method of claim 22, wherein the release is substantially osmotic pumping.

24. A method of claim 21, wherein the interfacial membrane is semipermeable and imperforate.

25. A method of claim 24, wherein the release is substantially osmotic pumping.